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Oregon Prescription Drug Affordability Board (PDAB)
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Re: Concerns with Selection of KEYTRUDA® (pembrolizumab) for Affordability Review

Members of the Oregon Prescription Drug Affordability Board,

Merck appreciates the opportunity to submit the following comments in response to the Board's decision to select KEYTRUDA for an affordability review and the process by which the Board will collect and assess data to support affordability reviews. As stated in our prior comments, we remain opposed to the selection of KEYTRUDA for affordability review and have significant concerns with the planned review process:

1. Merck is strongly opposed to the selection of KEYTRUDA for affordability review given its 10 orphan drug designations, as drugs with orphan-designated indications are excluded from affordability reviews under the PDAB statute.
2. The Board's plan to review KEYTRUDA not only conflicts with the PDAB statute but creates inconsistencies with the methodologies and processes utilized during the 2025 affordability cycle by implementing a flawed system of carving out drug use for orphan conditions.
3. The Board's proposed carve-out of patients with orphan indication claims introduces serious information lapses – particularly regarding the required consideration of health equity and stakeholder input – effectively silencing perspectives pertaining to orphan conditions.
4. The Board's review timelines and experimental methodologies do not allow for a careful review and underscore why the appropriate course is withdrawal.

The Board's Plan to Subject Orphan Drugs to Review by Evaluating a Subset of Utilization Creates Serious Process Flaws.

The Board's interpretation that drugs with orphan designation are eligible for review provided the review is limited to non-orphan utilization of the drug is not supported by statute and results in inequities that will negatively impact Oregonians. The broad removal of claims from patients with conditions requiring the use of orphan-designated drugs does not protect patients from the potential unintended consequences of an affordability review, as the statute contemplates.

As Merck explained in its April 10, 2026 submission, KEYTRUDA is ineligible for any affordability review.[1] ORS 646A.694(2) states that a drug – *not an indication or specific use* – designated by FDA under 21 U.S.C. § 360bb as a drug for a rare disease or condition "is not subject to review,"[2] and OAR 925-200-0020(1)(m) likewise states that such a prescription drug – *not an indication or specific use* – "is not subject to an affordability review."[3] The April 15 carve-out strategy simply operationalizes the Board's disputed interpretation by deleting orphan-coded claims and pressing forward with the review anyway. It does not resolve the issue created by selecting a drug that conflicts with the statute; it compounds it by making protected patients invisible in the affordability review but ultimately subjecting them to the outcome of the review. Merck therefore respectfully urges the Board to withdraw KEYTRUDA from the 2026 review list entirely.

The Proposed Carve-Out Is an Ad Hoc Workaround That Departs from Board's Established Review Process.

The Board has not adopted a coherent methodology for conducting an affordability review of a drug with orphan-designated uses. Instead, staff have proposed a narrow APAC claims adjustment that removes certain orphan-coded claims while leaving unresolved how the same orphan/non-orphan distinction would apply to the rest of the affordability review. The April 15 presentation focused on isolating non-orphan claims in APAC data, but it did not explain how that limitation would apply to carrier data calls, manufacturer submissions, payer information, patient and caregiver input, provider feedback, advocacy organization comments, or the Board's own rubric domains. That omission matters because an affordability review is not merely a claims exercise. A methodology that modifies only one data source while failing to explain how the same limitation applies across the rest of the review is not a valid review framework.

The proposed carve-out also conflicts with how the Board treated orphan designation during the 2025 affordability cycle. In March 2025, PDAB staff stated that the statute indicated the Board "cannot review drugs that are orphan designated."[4] Consistent with that understanding, the Board used orphan status as a selection-stage screen: it removed orphan-designated drugs during preliminary filtering and excluded additional orphan-designated drugs after further vetting before finalizing the review list.[5] That process avoided the very problem now presented by the review of KEYTRUDA. Rather than exclude the drug from review as the statute requires, the Board now proposes to keep KEYTRUDA in the process and carve away selected utilization after the fact. That is a material change in approach, not a minor technical adjustment.

In addition, the carve out approach creates inconsistencies with how the Board has reviewed multi-indication products in the past. In 2025, the Board reviewed several multi-indication products as whole drugs.[6] It acknowledged their multiple approved uses, but it evaluated utilization, system spending, and patient burden on an aggregated product basis. The Board did not remove selected disease populations from those reviews or attempt to conduct partial affordability assessments based on a subset of indications. The proposed review of KEYTRUDA therefore creates a new and unexplained exception to the Board's own practice. That exception does not make KEYTRUDA eligible for review. It instead confirms that the Board is attempting to build a special process around a drug that should have been excluded.

The Proposed Carve-Out Would Distort Board's Ability to Consider Patients Interests.

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[1] Merck comment letter to Oregon PDAB, Apr. 10, 2026; https://dfr.oregon.gov/pdab/Documents/Letters/Merck-Keytruda-20260410.pdf, accessed April 23, 2026
[2] Or. Rev. Stat. § 646A.694(2), https://www.oregonlegislature.gov/bills_laws/ors/ors646a.html, accessed April 23, 2026
[3] Or. Admin. Rules § 925-200-0020(1)(m), https://secure.sos.state.or.us/oard/view.action?ruleNumber=925-200-0020, accessed April 23, 2026
[4] Oregon Prescription Drug Affordability Board Meeting, March 19, 2025. https://youtu.be/NR6Hznggs-I, accessed April 23, 2026
[5] Oregon Prescription Drug Affordability Board Meeting, March 19, 2025. https://youtu.be/NR6Hznggs-I, accessed April 23, 2026
[6] 2025 Affordability Review Archives. https://dfr.oregon.gov/pdab/Pages/archive/2025-review-archive.aspx, accessed April 23, 2026

Two areas in particular highlight how the proposed carve-out methodology damages patient interests. The first area is stakeholder input. Oregon's rule requires the Board to seek input from patients and caregivers, attempt to gather diverse socioeconomic perspectives, and seek feedback from scientific and medical experts, safety-net providers, and payers.[7] The 2025 affordability reviews noted more than 300 responses from patients, caregivers, clinicians, safety-net providers, and organizations.[8] A KEYTRUDA review defined around non-orphan utilization only would, by design, pre-screen out patients using KEYTRUDA for orphan-designated cancers, their caregivers, their treating specialists, and the advocacy organizations that represent those disease communities. That does not create a fuller record; it creates a narrower one.

The second area is the consideration of health equity. Oregon's rule requires the Board to consider whether pricing contributes to health inequities in communities of color, under-resourced communities, and regions with limited pharmacy access.[9] While the Board's rubric includes "Equity," the proposed methodology removes some of the patients using KEYTRUDA for orphan-designated cancers from the analytic frame before that equity review occurs, while expressly stating that the goal is to focus on "broader population impact."[10] That is the opposite of how the Board has handled equity in prior reviews. In its reviews of Jardiance and Xarelto, the PDAB evaluated disparities in disease burden, prescribing, and access across underserved populations for all patients;[11,12] in the reviews for Nurtec ODT and Ubrelvy, the PDAB examined underrepresentation of racial and ethnic minority groups in clinical trials and access barriers in practice for all patients.[13,14] A KEYTRUDA review that makes certain cancer patients invisible at the outset is not a complete equity review.

The Board Has Not Explained How its Exclusionary Approach Could be Applied to Consider Stakeholder Input.

The Board's proposed methodology for reviewing KEYTRUDA appears to exclude input from patients, caregivers, clinicians, and advocacy groups whose experience relates to conditions associated with orphan-designated drug use. That approach creates serious practical and procedural problems. Would patients and family members need to disclose the condition for which KEYTRUDA is prescribed before their views can be considered? Will clinicians and those with scientific or medical training be asked to limit their feedback to non-orphan indications? Would advocacy organizations representing rare-cancer communities be told their testimony is out of scope? And if any of these scenarios occur, how would staff verify those representations? Because the Board posts written comments on its website and conducts its meetings in public, any diagnosis-based screening would pressure stakeholders to place sensitive health information into a public forum simply to preserve their voice in the proceeding. If the Board does not require that disclosure, then it has no transparent way to decide which stakeholder input counts and which it must ignore due to its association with orphan-designated drug use. Either way, the proposed approach is not a meaningful or administrable stakeholder input process.

The Accelerated Timeline for Affordability Reviews Underscores the Need to Withdraw KEYTRUDA.

[7] Or. Admin. Rules § 925-200-0020, https://secure.sos.state.or.us/oard/view.action?ruleNumber=925-200-0020, accessed April 23, 2026
[8] 2025 Affordability Review Archives. https://dfr.oregon.gov/pdab/Pages/archive/2025-review-archive.aspx, accessed April 23, 2026
[9] Or. Admin. Rules § 925-200-0020, https://secure.sos.state.or.us/oard/view.action?ruleNumber=925-200-0020, accessed April 23, 2026
[10] Oregon Prescription Drug Affordability Board, Apr. 15, 2026 Document Package. https://dfr.oregon.gov/pdab/Documents/20260415-PDAB-document-package.pdf, accessed April 23, 2026
[11] Jardiance Affordability Review, V2.0. https://dfr.oregon.gov/pdab/Documents/Jardiance.pdf#page=8.69, accessed April 23, 2026
[12] Xarelto Affordability Review, V2.1. https://dfr.oregon.gov/pdab/Documents/Xarelto.pdf, accessed April 23, 2026.
[13] Nurtec ODT Affordability Review, V4.0. https://dfr.oregon.gov/pdab/Documents/NurtecODT.pdf, accessed April 23, 2026
[14] Ubrelvy Affordability Review, V4.0. https://dfr.oregon.gov/pdab/Documents/Ubrelvy.pdf, accessed April 23, 2026

The Board's accelerated 2026 review schedule further confirms that KEYTRUDA should be withdrawn from review, not forced into an improvised methodology. The schedule requires the Board to evaluate 10 prescription drugs and two insulin products across a compressed summer review cycle, while also collecting information from manufacturers, insurers, patients, the public, and other stakeholders, and analyzing cost trends, utilization patterns, affordability impacts, equity, access, patient out-of-pocket costs, and therapeutic alternatives. That would be demanding under ordinary circumstances. It is especially problematic here because the Board is attempting, for the first time, to review products that it identifies as having orphan-designated conditions while simultaneously creating a process to separate orphan and non-orphan uses of KEYTRUDA. The July placement of KEYTRUDA on this schedule demonstrates that the Board has not accounted for the clinical, data, privacy, equity, and stakeholder complexities created by applying a process originally developed for whole-product affordability reviews to a drug the statute excludes from review and that the Board now proposes to segment by indication. This timing does not support confidence in a careful review; and further underscores why the appropriate course is withdrawal.

For these reasons, Merck respectfully urges the Board to withdraw KEYTRUDA from review in its entirety. ORS 646A.694(2) does not authorize the Board to review a drug with FDA orphan designation by carving away orphan-coded claims and assessing only the remainder.[15] And even if the Board believed otherwise, the April 15 methodology is still a novel, selective, and subjective exercise that departs from PDAB's own precedents, distorts equity review, and excludes stakeholder perspectives. Proceeding further would not only exceed the Board's statutory authority; it would also undermine the Board's stated commitment to transparent, evidence-based, and meaningful review of prescription-drug affordability for patients in Oregon.

We thank the Board for the opportunity to provide written comments and look forward to engaging in the future.

Sincerely,

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[15] Or. Rev. Stat. § 646A.694(2)